

REMARKS:

Reconsideration of the outstanding rejections is respectfully requested for the reasons that follow.

Claim rejections - 35 U.S.C. §102, anticipation

Claims 1, 3, 4 and 8 were rejected as being anticipated by US Patent 6,093,814. Claims 1 and 8 as amended exclude tributylamine. Therefore, Applicants submit that claims 1, 3, 4 and 8 as amended overcome the anticipation rejection. Further, new claims 13-17 do not recite that "R₁ is hydrogen"; therefore, they are not anticipated by US Patent 6,093,814.

Claim rejections - 35 U.S.C. §112, indefiniteness

Claims 1, 3, 5-10 and 12 were rejected under 35 USC §112 as being indefinite. The Examiner contended the term "acyl" was indefinite. The Examiner contends that "[a]pplicants have provided several references, and there diversity is evidence that the term has not one generally accepted meaning."

In a non-published board opinion of 1999, ex parte Heine (Application No. 07/963,165, decided August 16, 1999), the Board decided the same issue, namely whether the term "acyl" is definite. Heine's specification (U.S. Patent Application No. 07/963,165) does not contain a specific definition of "acyl." The Board also recognized that the term "acyl" has been defined as a radical having the general formula RCO-, but also has been defined more broadly as including any radical, such RSO₂-, which is formed from an organic acid by the removal of the hydroxyl group." See ex parte Heine, pages 7-8. However, the Board refused to find the term "acyl" indefinite. The Board reasoned as follows.

Regardless of which definition of acyl is used, the examiner has the burden of explaining why, when interpreted by one of ordinary skill in the art in light of appellants' specification and the prior art, the term would cause appellants' claims to fail to set out and circumscribe a particular area with a reasonable degree of precision and particularity.

Ex parte Heine, at 8 (a copy is attached to this response for the Examiner's convenience).

Further, the MPEP directs as follows.

The examiner's focus during examination of claims for compliance with the requirement for definiteness of 35 U.S.C. 112, second paragraph, is whether the claim meets the threshold requirements of clarity and precision, not whether more suitable language or modes of expression are available. When the examiner is satisfied that patentable subject matter is disclosed, and it is apparent to the examiner that the claims are directed to such patentable subject matter, he or she should allow claims which define the patentable subject matter with a reasonable degree of particularity and distinctness. Some latitude in the manner of expression and the aptness of terms should be permitted even though the claim language is not as precise as the examiner might desire.

MPEP, 8th Ed., 5th Rev. section 2173.02. (emphasis in the original).

Moreover, the Federal Circuit held that “[a] patentee need not define his invention with mathematical precision in order to comply with the definiteness requirement.” Oakley, Inc. v. Sunglass Hut Int'l, 316 F.3d 1331, 1342 (Fed. Cir. 2003); Invitrogen Corp. v. Biocrest Manufacturing L.P., 424 F3d 1374, 76 USPQ2d 1741, 1747 (Fed. Cir. 2005). “The definiteness requirement … does not compel absolute clarity. Only claims not amenable to construction or insolubly ambiguous are indefinite.” Datamize LLC v. Plumtree Software Inc., 417 F3d 1342; 75 USPQ2d 1801, 1804 (Fed. Cir. 2005).

Applicants submit that the law requires neither mathematical precision nor absolute clarity. Therefore, following the guidance of the MPEP quoted above, the first question to be asked in the analysis of the claim language at issue “C₁-C₆ acyl” is if it is apparent that the claims are directed to the patentable subject matter. The cited prior art reference US 6,093,814 (“US814”) discloses a compound where R₁ is hydrogen. The claim clearly recites that “R₁ is hydrogen or an amino-protecting group, selected from C₁-C₆ acyl group optionally substituted with one or more chlorine or fluorine atoms, an alkyl- or aryl-oxycarbonyl group, or a trityl group wherein each benzene ring is optionally substituted with one or more methoxy and/or methyl groups…” “R₁ is hydrogen” basically means an unprotected amino group. The claim is distinguished from the cited reference and directed to the patentable subject matter insomuch as an amino protecting group (including C₁-C₆ acyl groups) is concerned.

The next question is then if the claim defines the subject matter with a reasonable degree of particularity and distinctness. As an initial matter, Applicants submit that it is clear that the term acyl is discussed in the context of an amino protecting group, and preparation of organic pharmaceuticals. Then, the question to be asked becomes clear. What would a person of ordinary skill in the organic pharmaceuticals art do to obtain an amino protecting group? Would he synthesize an amino protecting group from scratch, beginning from a drawing board with a list of theoretically possible structures? A reasonable person would rather pick up a catalog of a chemicals vendor such as Sigma-Aldrich-Fluka or Merck. Then, the reasonable person of ordinary skill in the art can easily determine what group listed in the catalog can reasonably fall within the scope of the claim.

If someone is not absolutely certain about the scope of C₁-C₆ with mathematical precision, he can simply choose, for example, C₁₀. If the competitor is not absolutely certain about the scope of acyl with mathematical precision regarding S, P or As, he can choose non-acyl amino protecting groups from the catalog. The patentee only needs to give a reasonable level of notice to the public about what he claims.

Therefore, because the present claims have no outstanding prior art rejections that hinge on whether or not acyl encompasses S, P or As or how one would exactly count C₁-C₆, and also a person of ordinary skill in the art of organic pharmaceuticals synthesis would review a commercial vendor's catalog to obtain an amino protecting group, instead of synthesizing it from scratch testing all theoretical possibilities, and determine with a reasonable certainty what falls or may fall within the scope of C₁-C₆ acyl, and what does not or would not, Applicants submit that the claim language "C₁-C₆ acyl group" sets out a particular area with a reasonable degree of precision and particularity; therefore, the claim language is not indefinite.

Applicants believe that the above discussion proves that the claim language is definite and, particularly in view of the Board's decision, the Examiner's insistence on "one generally accepted meaning" of the claim language is misplaced.

With regard to the McGraw-Hill dictionary, the Examiner argues the dictionary "says that this is RCO, when R is aliphatic, alicyclic or aromatic ... [and t]hat would exclude HCO, since H is none of these." (Emphasis added). However, the McGraw-Hill dictionary says that acyl is "a radical formed from an organic acid by removal of a hydroxyl group; the general formula is RCO, where R may be aliphatic, alicyclic or aromatic." (Emphasis added). Therefore, it is evident that the McGraw-Hill dictionary does not exclude hydrogen because the dictionary mentions aliphatic, alicyclic and aromatic as examples for the R group as indicated by the use of "may" and does not mean aliphatic, alicyclic and aromatic to be the exclusive and exhaustive list of the R group. Therefore, unlike the Examiner's allegation, the McGraw-Hill dictionary does not contradict our definition and claim 2.

Further, the Examiner argues that McGraw-Hill dictionary definition also excludes CIC(O) or HOC(O), but the Condensed Chemical Dictionary defines it "broadly, covering any organic radical, and thus would include something like CIC(O), as chloroformic acid." Applicants submit that this statement also does not correctly reflect what the two dictionaries say. As mentioned above, the McGraw-Hill dictionary defines acyl as "a radical formed from an organic acid by removal of a hydroxyl group; the general formula is RCO..." The Condensed Chemical Dictionary defines acyl as "an organic acid radical in which the OH group is replaced by some other substituent; RCO-." Except a few slight cosmetic differences, Applicants do not see any substantial difference in the definitions from the two dictionaries.

Further, the Examiner argues that the Wikipedia dictionary says "sulfonic acids, phosphonic acid and some others" and therefore in view of the different definitions in the three dictionaries, "there is no generally accepted meaning, but an assortment of meanings." However, the Wikipedia dictionary very clearly explains that the term "acyl" refers to "a functional group obtained from an acid by removal of a hydroxyl group" and goes on to say "[m]ost commonly, the acyl group is derived from a carboxylic acid. It therefore has the formula RC(=O)-, with a double bond between the carbon and oxygen

atoms (thus forming a carbonyl group), and a single bond between R and the carbon; R denotes the group that occurs in the original carboxylic acid RCOOH.”

Therefore, Applicants, submit that the definitions of the three dictionaries aligned below, show no substantial difference:

“a radical formed from an organic acid by removal of a hydroxyl group; the general formula is RCO...” (McGraw-Hill Dictionary);

“an organic acid radical in which the OH group is replaced by some other substituent; RCO-.” (Condensed Chemical Dictionary); and

“a functional group obtained from an acid by removal of a hydroxyl group ... the formula RC(=O)-...” (Wikipedia dictionary).

For the reasons set forth above, Applicants submit that the indefiniteness rejection based on the claim language ““C₁-C₆ acyl group” is overcome, and should be withdrawn. In addition, Applicants note that new claims 13-16 do not recite acyl.

Claims 1-10 and 12 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite based on the term “adduct.” In response, Applicants submit that claim 1 and new claim 15 define the term “adduct.” Support can be found at page 6, lines 5-9 and page 5, lines 5-8. Therefore, Applicants submit that the indefinite rejection based on the term “adduct” is overcome, and should be withdrawn.

Claim 12 was rejected under 35 U.S.C. § 112, paragraphs 1 and 2. Applicants submit that claim 12 as amended overcomes the rejection.

Claims 1-10 and 12 were rejected under 35 U.S.C. § 112, first paragraph, for not being enabled for solvates. The Office Action asserts that “the examples presented all failed to produce a solvate” and based on that assertion the Office Action argues “the evidence of the specification is thus clear: these compounds do not possess the property of forming solvates” and then concludes that “there is no evidence that such compounds even exist.”

First of all, it is noted that the specification need not contain an example if the invention is otherwise disclosed in such a manner that one skilled in the art would be able to participate without an undue amount of experimentation. MPEP, 8th Edition, 5th

Revision, Section 2164.02. Second, if the assertion above means that if someone follows the teachings of the present application, he would not be able to obtain a solvate, Applicants submit that MPEP, 8th Edition, 5th Revision, Section 2164.04 clearly states that in order to make an enablement rejection, "the Examiner has the initial burden to establish a reasonable basis to question the enablement provided for the claimed invention. ... The language should focus on those factors, reasons, and evidence that lead the Examiner to conclude that the specification fails to teach how to make and use the claimed invention without undue experimentation, or that the scope of any enablement provided to one skilled in the art is not commensurate with the scope of protections sought by the claim." Further, section 2164.05 dictates that "the Examiner should never make the determination based on personal opinion." (Emphasis in original).

The Office Action presumes (or concludes without giving any explanations) that the examples fails to produce a solvate, and then it is argued that the evidence of the specification is thus clear: these compounds do not possess the property of forming solvates (because it is presumed that the examples fails to produce a solvate and any discussion about the specification is skipped), and then again it is argued that there is no evidence that such compounds even exist.

Applicants respectfully point out that solvates are easily obtainable. Solvates are not something that forms very rarely or at least not readily. Applicants submit that there are solvates once someone dissolves a solute in a solvent in the solution. The generation of solvates is unavoidable in a solution. The solvent molecules surround the solutes and that is a solvate. Therefore, a person skilled in the art could not avoid generating a solvate when the person dissolves a solute in a solvent. Further, Applicants refer to page 8, line 18-page 9, line 7. This disclosure teaches not only solvates in a solution but also solvates produced by removing solvent in part or almost completely by drying off the solvent. Therefore, Applicants submit that the specification enables the pending claims to its fullest scope, the enablement rejection based on the

term "solvate" is improper, and should be withdrawn. Further, it is noted that new claim 16 is directed only to the adduct, and new claim 17 is directed only to the salt.

With regard to the Examiner's reference to US 2006/0094703 in connection with potential interference, Applicant submit that according to the general practices set out in MPEP 8th Edition, 5th Revision, section 2302, no suspension of prosecution of the present application should be entered because the Deshpande application (US 2006/0094703) received a final rejection, and therefore, Deshpande is not in condition for allowance. Further, the present application has an earlier effective filing date than Deshpande, and the junior party Deshpande has not made the showing required by 37 CFR 41.202(e).

Claim 11 was objected to as lacking a final period. Applicants submit that claim 11 as amended overcomes the objection.

In view of the foregoing, it is submitted that all pending claims are patentable and the application is in condition for allowance. The Commissioner is authorized to charge any fees or credit any overpayments to Deposit Account No. 02-2135.

Respectfully submitted,

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